

UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

X

UNITED STATES OF AMERICA; the States of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MASSACHUSETTS, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VIRGINIA, WASHINGTON and WISCONSIN, the DISTRICT OF COLUMBIA, THE CITY OF CHICAGO and THE CITY OF NEW YORK *ex rel.*, STEVEN M. CAMBURN,

USDC SDNY
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13-CV-3700 (KMW)

OPINION & ORDER

Plaintiffs,

-against-

NOVARTIS PHARMACEUTICALS CORPORATION,

Defendant.

X

KIMBA M. WOOD, United States District Judge:

In this *qui tam* suit, Relator Stephen M. Camburn (“Relator”) alleges that Defendant Novartis Pharmaceuticals Corporation (“Novartis”) engaged in an unlawful kickback scheme to induce physicians to prescribe Gilenya, a medication used to treat multiple sclerosis, in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq.*, the Anti-Kickback Statute, 42 U.S.C. § 1320a-7b, and analogous state and municipal laws. Novartis has moved to dismiss Relator’s Amended Complaint. Because Relator fails to plead the existence of a kickback scheme with adequate particularity, the Amended Complaint is dismissed, without prejudice to Relator to file a Second Amended Complaint by May 8, 2020.

BACKGROUND

I. Procedural History

Relator filed a sealed *qui tam* complaint against Novartis on May 31, 2013 (the “Complaint”), alleging that Novartis engaged in a fraudulent kickback scheme to induce doctors to prescribe Gilenya, in violation of the False Claim Act (“FCA”), the Anti-Kickback Statute (“AKS”), and analogous state and municipal laws. (ECF No. 16.) The FCA makes it unlawful to present false or fraudulent claims for payment to the federal government. *See* 31 U.S.C. § 3729. Private individuals, known as “relators,” may bring civil suits on behalf of the United States for violations of the FCA. *See id.* § 3730(b). The AKS prohibits, *inter alia*, offering or paying a “kickback, bribe, or rebate” in order to “induce” a person to “recommend” the purchase of any drug covered by a “Federal health care program.” 42 U.S.C. § 1320a-7b(b)(2). Any claim for services resulting from a violation of the AKS “constitutes a false or fraudulent claim,” and thus is actionable under the FCA. *Id.* § 1320a-7b(g).

On September 1, 2017, the United States, along with all the States and municipalities on whose behalf the Complaint was brought, informed the Court that it had investigated Relator’s claims and decided not to intervene. (ECF No. 18.) The Complaint was then unsealed. (ECF No. 15.)

On August 20, 2018, Novartis moved to dismiss the Complaint. (ECF Nos. 24–25.) On September 10, 2018, before that motion was decided, Relator amended the Complaint (the “Amended Complaint”). (ECF Nos. 26–27.) Novartis then moved to dismiss the Amended Complaint. (ECF Nos. 28–29.) The United States submitted a Statement of Interest, setting forth its view that Novartis’ motion to dismiss the Amended Complaint misstated the law regarding scienter in the FCA context. (ECF No. 35.)

II. Facts

Novartis manufactures Gilenya, a medication the Food and Drug Administration approved in September 2010 to treat multiple sclerosis. (Amended Complaint (“AC”) ¶¶ 8, 88.) From August 2010 until July 22, 2013, Relator worked as an Executive Sales Specialist at Novartis in the Philadelphia area. (*Id.* ¶¶ 8–9.)

Novartis promoted Gilenya using “speaker events.” At the speaker events, a healthcare professional, usually a doctor, was paid to educate an audience about the benefits and drawbacks of Gilenya. (*Id.* ¶ 106.) At “Peer-to-Peer” events, the speaker addressed other healthcare professionals; at “Patient Events,” the speaker addressed prospective patients. (*Id.*) Novartis paid a per-event honorarium of \$1,500 to \$3,500 to its speakers. (*Id.* ¶ 98.) Speaker events typically took place at high-end restaurants. (*Id.* ¶ 106.) Novartis employed five speakers in Relator’s Philadelphia region, four of whom were doctors and one of whom was a nurse. In 2012, the four prescribing speakers accounted for 43% of Gilenya prescriptions written in the Philadelphia region. (*Id.* ¶ 111.)

According to Relator, the speaker events did not actually serve their stated purpose of educating healthcare professionals and prospective patients about Gilenya, but were in fact designed to provide a facially legitimate means for Novartis to funnel kickbacks, in the form of honoraria and lavish meals, to speaker-doctors who prescribed high volumes of Gilenya.

Relator alleges that the speaker events did not fulfill their purported educational function. Speakers would often present to other paid speakers, their own medical groups, physicians and patients who had already attended Gilenya speaker events, or to no one at all. (*Id.* ¶ 95.) Novartis provided slide decks for presenters to use at speaker events, but the slides repeated the drug package label insert information and the information that sales representatives provided to doctors at weekly office visits. (*Id.* ¶ 96.) In Relator’s experience, speakers presented the full

slide deck at only 10% of Peer-to-Peer Events and 20-30% of Patient Events. Relator recalls that speakers usually presented the slides for about twenty minutes. (*Id.*) Relator does not specify whether the full slide deck was or could be presented in this time period.

Relator also alleges that the speaker events often exceeded Novartis' internal spending limits, which Relator claims indicates that the true purpose of the speaker events was to provide speakers with a lavish meal. Novartis had a \$125 per attendee spending limit for meals at speaker events. (*Id.* ¶ 101.) Relator identifies five examples of speaker events that went over-budget. (*Id.* ¶¶ 103–04.) Relator also alleges that Novartis' sales staff would often alter Novartis' internal records to conceal the excessive spending. (*Id.* ¶¶ 102–03.) For each of the aforementioned five over-budget events, Relator states that sales staff added false attendees, "room charges," and other false expenses to conceal the excessive spending. (*Id.* ¶¶ 103–04.)

Relator claims Novartis perpetrated this scheme from 2010 or 2011 through September 10, 2018, the date of the Amended Complaint. (*Id.* ¶ 14.)

LEGAL STANDARD

A complaint must be dismissed if it fails to state a claim upon which relief can be granted. Fed. R. Civ. P. 12(b)(6). "To survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Aschroft v. Iqbal*, 556 U.S. 662, 678 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)).

In addition, Rule 9(b) of the Federal Rules of Civil Procedure ("Rule 9(b)") requires that a complaint "alleging fraud or mistake . . . must state with particularity the circumstances constituting fraud or mistake." The "adequacy of particularized allegations under Rule 9(b) is . . . case- and context-specific." *United States ex rel. Chorches v. Am. Med. Response, Inc.*, 865

F.3d 71, 81 (2d Cir. 2017) (citation omitted). As an exception to this rule, “allegations may be based on information and belief when facts are peculiarly within the opposing party’s knowledge.” *Id.* at 81–82 (citation omitted).

“The purpose of Rule 9(b) is threefold—it is designed to provide a defendant with fair notice of a plaintiff’s claim, to safeguard a defendant’s reputation from improvident charges of wrongdoing, and to protect a defendant against the institution of a strike suit.” *O’Brien v. Nat’l Prop. Analysts Partners*, 936 F.2d 674, 676 (2d Cir. 1991) (citation and quotation marks omitted). District courts must “rigorously enforce” the requirements of Rule 9(b). *Ross v. Bolton*, 904 F.2d 819, 823 (2d Cir. 1990).

Plaintiffs alleging FCA claims premised on violations of the AKS must plead both the FCA violation and the underlying kickback scheme in compliance with Rule 9(b). *United States ex rel. Polansky v. Pfizer, Inc.*, 822 F.3d 613, 617–18 (2d Cir. 2016); *United States ex rel. Bilotta v. Novartis Pharm. Corp.*, 50 F. Supp. 3d 497, 513–14 (S.D.N.Y. 2014) (Gardephe, J.). Claims pled under FCA-analogous state and municipal laws must also be pled in compliance with Rule 9(b). *United States ex rel. Arnstein v. Teva Pharms. USA, Inc.*, No. 13-CV-3702, 2016 WL 750720, at *11 (S.D.N.Y. Feb. 22, 2016) (McMahon, J.)

DISCUSSION

Novartis claims the Amended Complaint should be dismissed for three reasons: first, because Relator fails to plead the existence of the alleged kickback scheme with adequate particularity; second, because Relator fails to plead the existence of false claims with adequate particularity; and third, because relator fails to plead scienter on the part of Novartis. The Court finds that the Amended Complaint fails to plead the existence of a kickback scheme with adequate particularity, and thus dismisses the Amended Complaint without addressing Novartis’

other contentions.

I. The Amended Complaint Does Not Plead the Existence of a Fraudulent Scheme With Adequate Particularity.

Novartis contends that the Amended Complaint fails to plead the existence of a kickback scheme with adequate particularity to satisfy Rule 9(b). General assertions about an alleged scheme, unsupported by examples and details, typically are insufficient to satisfy Rule 9(b). *See United States ex rel. Smith v. New York Presbyterian Hosp.*, No. 06-CV-4056, 2007 WL 2142312, at * 6 & n. 43 (S.D.N.Y. July 18, 2017) (Buchwald, J.); *see also United States ex rel. Corp. Compliance Assocs. v. New York Soc'y for the Relief of the Ruptured and Crippled*, No. 07-CV-292, 2014 WL 3905742, at *22 (S.D.N.Y. Aug. 7, 2014) (Castel, J.) (absence of examples of fraudulent conduct “further underscores the Complaint’s failure to plead with particularity violations of the Anti-Kickback Statute”). But, where a plaintiff pleads the existence of an extensive, lengthy kickback scheme, plaintiff need not “plead the specifics with respect to each and every instance of fraudulent conduct.” *Bilotta*, 50 F. Supp. 497 at 517 (citation omitted). Instead, “in setting forth a complex and far-reaching scheme, the [plaintiff] need allege only representative samples of fraudulent conduct to satisfy Rule 9(b).” *Id.* at 518 (citation and quotation marks omitted).

The crux of Relator’s allegation about the speaker events is that Novartis paid speakers to present the same uninformative slides to audiences who had already seen the presentation before or were otherwise unsuited to learn from the presentation, all while the speaker and other attendees ate a lavish meal at Novartis’ expense. According to Relator, these allegations demonstrate that the true purpose of the events was to provide kickbacks, in the form of speaker honoraria and lavish meals, to speakers who prescribed high volumes of Gilenya, rather than to serve a legitimate educational purpose.

The alleged kickback scheme is similar to the schemes alleged in two recent cases in this District, *Bilotta* and *Arnstein*. In both, plaintiffs claimed that pharmaceutical companies violated the FCA and AKS by using sham speaker programs to funnel kickbacks, in the form of honoraria and lavish meals, to doctors in exchange for prescribing certain pharmaceutical drugs. *See Arnstein*, 2016 WL 750720, at *16; *Bilotta*, 50 F. Supp. 3d at 515–16. In both cases, the court found that the alleged kickback schemes were pled with adequate particularity to satisfy Rule 9(b). Both courts emphasized that the operative complaints contained detailed allegations, illustrated by specific examples, of how the sham events worked. In *Bilotta*, in addition to generally alleging that the speaker events were too repetitive to be educational, plaintiff's complaint

Describe[s] specific examples of alleged sham speaker events, as well as specific doctors who were repeat speakers or attendees. In particular, [plaintiff] lists twelve doctors who were paid as speakers by Novartis to give the same presentation to the same group of doctors over short periods of time. [The complaint] identifies the time period during which each doctor attended these speaker events, the name of the presentations, the number of repeat attendees, the doctor's geographic location, and—for several of the speakers—the amount of compensation they received from Novartis.

Bilotta, 50 F. Supp. 3d at 516. Likewise, in *Arnstein*, the complaint

provides several examples of allegedly sham programs, including one in which four physicians met monthly with one another and Teva sales representatives, and rotated the duty of giving a 15 minute presentation to each other on one of a set number of rote topics. The doctors were paid \$1500 each time they presented. In a different “program” two physicians and two Teva employees sat down to dinner; no presentation was made and no new material discussed, but each physician received \$2,000 for the “program.” On another occasion, a physician sat down to dinner with a single Teva representative, presented no medical materials, and was paid \$2,000. The Complaint provides several more examples of such generosity.

Arnstein, 2016 WL 750720, at *4 (citations omitted). Recognizing the importance of these examples to satisfying Rule 9(b), the *Bilotta* court noted that, although plaintiff provided examples of sham speaker presentations given by thirteen of the fifteen doctors discussed in its

complaint, plaintiff failed to provide such details about two of the doctors. 50 F. Supp. 3d at 516 n.8. The court declined to “consider[] these two doctors in determining the sufficiency of the [operative complaint].” *Id.*

Here, the Amended Complaint lacks the detailed allegations and representative examples that enabled the *Bilotta* and *Arnstein* complaints to survive dismissal under Rule 9(b). Relator presents five examples of speaker events to illustrate his general allegations: a January 31, 2013 event at which Dr. H.W. spoke; an April 9, 2013 event at which Dr. S.R. spoke; an April 11, 2013 event at which Dr. H.C. spoke; a June 11, 2013 event at which Dr. R.B. spoke; and an August 22, 2012 event at which Dr. M.K. spoke. (AC ¶¶ 103–04.) The Amended Complaint alleges that each of these events took place at a high-end restaurant and exceeded Novartis’ \$125 per attendee internal budget limit, and that sales personnel altered Novartis’ internal records to conceal the excess. The Amended Complaint provides no further details about the events involving Drs. H.W., S.R., H.C., and R.B., aside from a headcount of attendees and the names of the Novartis personnel who organized the events. (*Id.*)

Relator provides slightly more detail about Dr. M.K.’s speaker event, but fails to allege that this event was representative of the alleged scheme. The Amended Complaint states that Dr. M.K.’s August 22, 2013 event in Philadelphia was attended by ten people, including doctors, nurses, medical students, and medical assistants, as well as Relator and several other Novartis employees. (*Id.* ¶¶ 103, 123.) The bill exceeded Novartis’ \$125 per attendee spending limit. (*Id.*) The Novartis account manager who organized the event added fictitious names to the attendance sign-in sheet to reduce the price per person. (*Id.* ¶ 124.) The Amended Complaint does not allege that any of the attendees had attended other Gilenya speaker events or were otherwise improper, or make any allegations about the educational value of Dr. M.K.’s

presentation.¹

Thus, the examples in the Amended Complaint are representative of Relator's general allegations only with respect to the allegation that the speaker events exceeded Novartis' internal spending limits. The fact that some speaker events went over-budget, and that Novartis salespeople concealed the excess spending in Novartis' internal records, is not enough to allege a kickback scheme orchestrated by Novartis. This is particularly so because the Amended Complaint makes no allegations about why sales personnel concealed the excessive spending, whether they were instructed to do so, who the falsification was meant to deceive, or what role the falsification played in the alleged kickback scheme.

All of the other allegations about the speaker events in the Amended Complaint—that the speaker events lacked educational value, were given to repeat attendees, were given by one paid speaker to another, were given to no one at all, etc.—are unsupported by such concrete details as the dates on which individual events took place, the names of the speaker and the audience members, whether the attendees attended other speaker events, or the content of the speakers' presentations. Although Relator claims that Novartis' slide deck was sometimes not fully presented, Relator does not tether this allegation to any specific events, or explain whether events at which the slide deck was partially or fully presented served an educational purpose.

Although specific examples of fraudulent events may not always be necessary to adequately plead a fraud case like the one Relator alleges, the Court finds that the absence of

¹ The Amended Complaint alleges that Dr. M.K. did not live in Philadelphia, and that he requested, and was given, three speaker events during the trip to Philadelphia. The August 22, 2013 event was one of these speaker events. (AC ¶ 123.) This allegation leaves unclear whether the individual events served a legitimate purpose. Furthermore, the Amended Complaint does not explain why Dr. M.K.'s unwillingness to travel to Philadelphia without the promise of multiple speaking engagements was unreasonable, let alone how it would prove that the speaker events functioned as kickbacks. The Amended Complaint does not even allege from where Dr. M.K. was travelling. Without further detail, the Court cannot evaluate the propriety of Dr. M.K.'s trip to speak in Philadelphia.

such examples requires dismissal in this case. Relator claims he attended and organized speaker events, yet he fails to state that any one of them was sufficiently representative of other speaker events. *See Concha v. London*, 62 F.3d 1493, 1503 (9th Cir. 1995) (“Rule 9(b) . . . requires that plaintiffs specifically plead those facts . . . to which they can reasonably be expected to have access.”). Without specific details and concrete examples of the fraudulent conduct involved in the multi-year, nationwide kickback scheme that Relator alleges, Novartis would be hard-pressed to respond to Relator’s Amended Complaint or even to know which events were allegedly fraudulent. The Court likewise cannot evaluate whether the Gilenya speaker events were fraudulent on the basis of the allegations contained in the Amended Complaint.

The Amended Complaint’s allegations about other indicia of fraud fare no better under Rule 9(b). For instance, Relator alleges that Novartis paid doctors honoraria for events that Novartis cancelled, a practice that purportedly shows that the true purpose of the events was to pay honoraria, not to educate. (AC ¶ 99.) Relator alleges that Novartis paid speakers a total amount of approximately \$500,000 between 2011 and 2013, for over 250 cancelled events, and identifies three doctors—Drs. J.B., A.B., and B.K.—who allegedly received payments for cancelled events and wrote high volumes of Gilenya prescriptions. (*Id.*) Relator fails to identify a single cancelled event, let alone the circumstances or timing of the cancellation. Relator presents no anecdotal or statistical data from which the Court could infer that the cancellations were part of a kickback scheme. Although Relator claims Novartis stopped paying for cancelled programs in 2013, when the United States charged Novartis with conducting sham speaker programs in relation to some cardiovascular drugs, Relator alleges no connection between those charges and the Gilenya speaker program. This lack of detail leaves the Court unable to evaluate the legitimacy of these cancellations and does not give Novartis notice of which cancellations

were allegedly improper.

The Amended Complaint also alleges that Novartis improperly supplied doctors with marketing DVDs. The Amended Complaint alleges that Novartis provided speakers with customized DVDs to provide to patients, which were intended to help doctors recruit new patients and thus improve Gilenya’s market share. (*Id.* ¶ 105.) The Amended Complaint does not state in what way or ways Novartis’ supplying doctors with DVDs advanced the purported fraud.

The Amended Complaint also alleges that Novartis scheduled so many speaker events that the events could not have served a legitimate purpose. The Amended Complaint alleges that Vince Schaeffer, the supervising manager of Relator’s Philadelphia region, required his sales team to schedule 96 Patient Events and 32 Peer-to-Peer Events in 2012. (*Id.* ¶¶ 106–07.) Relator claims this was an “excessive and unnecessary” number of events (*Id.* ¶ 109) that was higher than the number of events held by Novartis’ competitors (*Id.* ¶ 107). Relator states that the 2,000 speaker events held in 2013 were excessive relative to the 400,000 multiple sclerosis patients in the United States. (*Id.* ¶¶ 93, 127.) But the Amended Complaint supplies no basis for Relator’s contention that the events were so numerous as to indicate that they were part of a kickback scheme. The Amended Complaint alleges that Novartis did not use “needs-assessment” to determine the number of speaker events (*Id.* ¶ 97), but this allegation does not, without more detail, adequately allege that the number of events was driven by an intention to bribe doctors to prescribe Gilenya.

Relator’s allegations about Novartis’ return-on-investment analysis suffers from the same deficiency. Relator alleges that Novartis tracked each speaker’s prescriptions to determine the ROI of the speaker program, and “engaged in conversations with the sales force when physicians

. . . were not meeting minimum prescription levels.” (*Id.* ¶ 133.) When a speaker’s prescriptions decreased, Novartis “would want to know why and would often discuss whether using a different speaker or reducing a speaker’s commitments was necessary under the circumstances.” (*Id.*)

The Amended Complaint does not clearly allege what actions, if any, Novartis took on the basis of its ROI analysis, or allege a single example of an occasion on which any such action was taken.² The Amended Complaint does not allege a relationship between any doctor’s prescribing activities and his or her participation in the Gilenya speaker program. Relator alleges that the four doctor-speakers in his Philadelphia region were high-prescribers, but does not allege that Novartis selected its speakers based on their prescribing habits, or that any speaker prescribed more Gilenya after joining the speaker program. In *Bilotta*, by contrast, the operative complaint alleged that Novartis tracked the ROI of its speaker events and invited doctors to be speakers based on the number of prescriptions a speaker wrote for Novartis drugs, and supplied specific examples of speakers whose prescribing activity and speaking assignments increased in tandem.

See Bilotta, 50 F. Supp. 3d at 503, 516–17. Likewise, in *Arnstein*, the operative complaint alleged that Teva permitted speakers to continue speaking only if they met minimum prescription requirements and “added” speakers based on its ROI analysis. *See Arnstein*, 2016 WL 75020, at *3, 16–17. The *Arnstein* complaint also alleged specific examples of doctors who were denied further speaker engagements because of their decreasing prescription numbers. *See id.* Such specific descriptions of the role of ROI analysis in the kickback scheme are missing from the instant Amended Complaint.

² The Amended Complaint does allege that Schaeffer “had little to no interest” in using the services of Novartis’ one non-doctor speaker, who was a registered nurse, because Schaeffer believed a non-prescribing speaker would generate insufficient ROI. (AC ¶ 120.) But this allegation is undercut by Relator’s allegation that this nurse spoke ten times in 2012, less than the 17.5 times the average doctor speaker spoke, but not a number plausibly indicative, without more explanation, of “no interest.” (*Id.* ¶ 112.) In any event, whether Novartis employed nurses to speak at Patient Events says little about whether Novartis used speaker events to reward doctors for prescribing Gilenya.

Finally, Relator's allegations of statements by Novartis personnel do not make up for the inadequacies in the Amended Complaint. Relator claims, for instance, that Schaeffer, Relator's supervising manager, stated, on one occasion, that the true value of the speaker events was "taking care of the speaker." (AC ¶ 113.) Relator also alleges that James Pizano, a strategic account manager, stated that, because Novartis was scheduling fewer speaker events in 2013, the company would have to find new ways to "show [a high-prescribing doctor] love and keep him happy." (*Id.* ¶ 118.) Neither of these statements, nor any of the other ones Relator identifies, is tied to any actions taken by Novartis, and none explicitly refers to kickbacks. In the absence of sufficiently particularized allegations about the alleged kickback scheme itself, these statements do not render the Amended Complaint compliant with Rule 9(b).

Taken together, the allegations in the Amended Complaint do not adequately plead the existence of a kickback scheme with sufficient particularity to satisfy Rule 9(b). The Court therefore dismisses the Amended Complaint.³

II. Relator is Granted Leave to Amend His Complaint.

"District courts typically grant plaintiffs at least one opportunity to plead fraud with greater specificity when they dismiss under Rule 9(b)." *ATSI Commc'ns, Inc. v. Shaar Fund, Ltd.*, 493 F.3d 87, 108 (2d Cir. 2007). Here, Relator has amended his complaint only once, as of right. The Court accordingly grants Relator leave to amend his complaint.

The Court does not reach Novartis' contentions that the Amended Complaint must be

³ The Court is not persuaded by Relator's supplemental authority, *Purcell v. Gilead Scis., Inc.*, No. 17-CV-3523, 2020 WL 762473 (E.D. Pa. Feb. 13, 2020). The allegations in *Purcell* were far more specific than those in the instant Amended Complaint. For instance, the plaintiff in *Purcell* made detailed allegations about how the defendant pharmaceutical company used data analysis to identify high prescribers for inclusion in its advisory board and speaker programs; about how, on one occasion, defendant granted a doctor's request to be included in an advisory board meeting because the program offered convenient free travel, even though the doctor's presence served no legitimate business purpose; how the vast majority of high prescribers of defendant's pharmaceutical drug were paid participants in speaker programs and advisory boards; and how defendant invited so many doctors to a particular advisory board meeting that it was unlikely the meeting could serve a legitimate purpose. *See id.* at *3–5. In addition, of course, *Purcell* does not bind this Court.

dismissed because it (1) fails to plead the existence of false claims with sufficient particularity and (2) fails to adequately plead scienter on the part of Novartis. The Court also does not reach the United States' Statement of Interest, which sets forth the United States' position on the law of scienter in the context of this case. The Court cannot productively address these contentions until (and if) Relator sufficiently alleges the existence of the kickback scheme upon which the falsity of the alleged claims is premised.

CONCLUSION

For the foregoing reasons, the Court grants Novartis' motion to dismiss, pursuant to Rule 9(b), and grants Relator leave to amend his complaint by May 8, 2020, to comply with Rule 9(b)'s requirements.

SO ORDERED.

Dated: New York, New York
March 24, 2020

/s/ Kimba M. Wood
KIMBA M. WOOD
United States District Judge